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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,002	02/17/2006	Hisashi Narimatsu	159-88	8959
23117 7590 06/15/2007 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER BAUSCH, SARAE L	
			ART UNIT 1634	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/534,002

Applicant(s)

NARIMATSU ET AL.

Examiner

Sarae Bausch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>05/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to applicants correspondence mailed 03/08/2007. The amendment to the claims mailed 03/08/2007 has been entered

Election/Restrictions

2. Applicant's election with traverse of group I, claims 1-4 and 6, SEQ ID No. 1 and in response to examiner further restriction, applicants elect group 1, claims 1-4 and 6 in the reply filed on 03/08/2007 is acknowledged. The traversal is on the ground(s) that Kitagawa et al. does not establish that unity of invention is lacking because its sequence is not the same as SEQ ID no. 1, encoding a chondroitin synthase as in the present invention. The response asserts that the sequence that is taught by Applicants is a special technical feature shared in common by the claims. This is not found persuasive because the special technical feature that is shared among the claims a gene coding for chondroitin synthase protein and does not require that the chondroitin synthase gene has the sequence depicted in SEQ ID No. 1. Furthermore, examination of more than one nucleotide sequence would be a serious burden, as stated in the MPEP 803.04, the complex nature of the claimed material may necessitate the reasonable number of sequences to be less than ten. Searching a composition comprising any combination of six nucleotide sequences, requires search all 6 sequences, which is a significant number of sequences to examine. The office would have to search each combination of six sequences which would be a search burden to the office as the demand on the PTO's computers dedicated to sequence searches alone would be undue as would the time the

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examiner would need to review the finding of all 6 searches. In the instant case, the search burden to examine up the combination of six sequences is a search burden. Furthermore, the claimed nucleic acids lack unity of invention because the instantly claimed nucleic acids have different sequences and can be used to detect different sequences and therefore have different structure and function and lack unity of invention and therefore it is proper to restrict the patentably distinct and independent inventions under 35 USC 121.

The requirement is still deemed proper and is therefore made FINAL:

3. Claim 5 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 03/08/2007.
4. Currently, claims 1-4, and 6 are under examination as the claims read on mutation of a gene coding for chondroitin synthase protein, SEQ ID No. 1 and encodes amino acid sequence SEQ ID No. 2.

Specification

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see page 15. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112- Second Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a). Claim 1 is vague and indefinite. Claim 1 is drawn to a method for detecting Paget disease of bone, however the final process step is associating Paget disease of bone with the mutation of a gene condign for a chondroitin synthase protein. Accordingly the claims are ambiguous because the preamble, detecting Paget disease of bone and the process step of associating Paget disease of bone with the mutation of a gene condign for a chondroitin synthase protein does not have to encompass the detecting Paget disease of bone and therefore it is not clear that detecting the associating Paget disease of bone with a mutation of a gene coding for a chondroitin synthase protein will *necessarily* result in detecting Paget disease of bone. Therefore, the limitation in the preamble is not recited in the process steps, the metes and bounds of the claim are vague and indefinite, and it is unclear if one necessarily accomplishes what is intended for the method by practicing the recited method step(s).

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(b). Claim 1 recites the limitation "the mutation" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim. However, claim 1 does not recite "a mutation" and it is unclear which mutation of a gene coding for chondroitin synthase protein has an association of Paget's disease.

(c). Claims 2-4 and 6 depend from claim 1 and are therefore vague and indefinite for the reasons applied to claim 1.

Claim Rejections - 35 USC § 112-Description

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-4 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is referred to the revised interim guidelines on written description published January 5, 2001 in the Federal Register, Volume 66, Number 5, page 1099-111 (also available at www.uspto.gov).

The rejected claims are broadly drawn to methods for detecting Paget disease comprising determining a mutation of a gene coding for a chondroitin synthase protein. The rejected claims provide no structural limitation regarding what is encompassed by

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the term gene coding for chondroitin synthase protein or wherein the chondroitin synthase protein is a glycosyltransferase.

When the claims are analyzed in light of the specification, the instant invention encompasses methods comprising the analysis of an enormous and wide variety of nucleic acid sequences. The claims are broadly drawn detecting Paget disease by determining a mutation of a gene coding for a chondroitin synthase protein or a mutation in the chondroitin synthase protein is a glycosyltransferase. The specification teaches a broad definition of 'chondroitin synthase protein' as any enzyme that takes part in the synthesis of chondroitin or chondroitin synthase, which can broadly encompass any enzyme that is involved in cell repair, cell metabolism, etc. Thus the rejected claims encompass analysis of any portion of any variant of any enzyme that takes part in the synthesis of chondroitin or chondroitin sulfate from any organism, which may include gene sequences very different from the disclosed SEQ ID NO: 1, and genes that encode polypeptides very different from the disclosed SEQ ID NO: 2, including sequences containing any polymorphisms (e.g. any insertion, deletion, or repeat at any location within the gene) and mutations not taught by the instant specification and not yet known in the art. In analyzing whether the written description requirement is met for genus claims for genus claims, it is first determined whether a representative number of species have been described by their complete structure. Nucleic acids of such a large genus as encompassed by the rejected claims have not been taught by the specification. The specification of the instant application discloses only SEQ ID NO: 1 (a chondroitin synthase gene), and SEQ ID NO: 2 (the amino acid sequence encoded by SEQ ID NO: 1).

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Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e. other than nucleotide sequence, gene name, and specific polymorphic position), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case, the specification provides only the sequence of the chondroitin synthase gene (SEQ ID NO: 1) and the encoded amino acid sequence (SEQ ID NO: 2). The specification does not provide any characteristics that would allow one to identify any other genes from another organism or any particular portions or fragments or variants of the disclosed sequence that would allow for the diagnosis of cancer based on amplification of the non-disclosed gene.

Applicants' attention is directed to the decision in *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In *re Soll*, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In *re Wahlforss et al.*, 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

In the instant application, with the exception of a method for determining the sequence of a chondroitin synthase gene, SEQ ID No. 1 and amino acid that encodes SEQ ID No. 2, one of skill in the art cannot envision the detailed chemical structure of the encompassed polynucleotides (i.e. any chondroitin synthase protein associated with Pagets disease), regardless of the complexity or simplicity of the method of identification.

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Adequate written description requires more than a mere statement that any genetic variants or fragment of the gene is part of the claimed invention and a qualitative description of the nature of the variant (e.g. associated with Paget Disease). The nucleic acid itself is required.

In conclusion, the limited information provided regarding the association of a mutation in a gene coding for a chondroitin synthase protein gene (including disclosure only of SEQ ID NO: 1 and 2) and its association with Pagets is not deemed sufficient to reasonably convey to one skilled in the art that Applicant is in possession of methods comprising the detecting Paget diseases of bone by associating Paget disease of bone with the mutation of a gene coding for a chondroitin synthase protein besides those particularly disclosed in the specification at the time the application was filed.

Thus, having considered the breadth of the claims and the provisions of the specification, it is concluded that the specification does not provide adequate written description for the claims.

Claim Rejections - 35 USC § 112- Enablement

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*; 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

“Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the

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predictability or unpredictability of the art, and (8) the breadth of the claims.”

The nature of the invention and the breadth of the claims

The claims are drawn to methods for detecting Paget’s disease of bone by associating Paget disease of bone with the mutation of a gene coding for a chondroitin synthase protein. The claims are further drawn to detecting Paget disease of bone wherein the chondroitin synthase protein is a glycosyltransferase having activity for transferring a D-glucuronic acid residue or an N-acetyl-D-galactosamine residue to the saccharide residue at the non-reducing terminal of chondroitin or is glycosyltransferase by means of which a xylose residue linked to an amino acid residue has D-galactose linked thereto by a b1,4-glyoside linkage. The claims are further drawn to determining a mutation ins SEQ ID No. 1 or a gene encoded by SEQ ID No.2

The rejected claims encompass analysis of any individual, including human and non-human. The rejected claims encompass any type of Paget disease of bone and detection of any mutation in any gene coding for a chondrotin synthase protein, which encompasses as defined by the specification as any enzyme that takes part in the synthesis of chondroitin or chondroitin syntheses (see page 5, lines 19-25) and can broadly encompass any enzyme that is involved in cell repair, cell metabolism, etc.

The nature of the claim requires knowledge of a correlation between the detection of the presence of a mutation in any gene coding for a chondroitin synthase protein and its predisposition to Paget’s disease.

Guidance in the Specification

The specification asserts that a gene mutation means a structural change in gene and mutation can encompass point mutation, inversion, deletion, insertion, duplication and translocation. The specification asserts that a mutant gene means a nucleotides sequence as depicted in SEQ DI N1 provided that one or more nucleotides are replaced or deleted or that one or more nucleotides are inserted or added (see page 14, lines 3-14). However the specification does not teach an association of any mutation within SEQ ID No. 1 and its association with Pagets disease of the bone.

The specification asserts that Paget disease of bone can be detected by confirming the presence of mutation in a chondroitin synthase gene (see page 17, lines 13-15). The specification asserts that the peripheral blood of a patient with Paget disease of bone is compares with the nucleotides sequence of the chondroitin synthase gene extracted from mononuclear cells in normal peripheral blood and detect of any mutation can be identified as indicative of Paget Disease of bone (see page 17, lines 13-25). However, this assertion is merely prophetic. The specification does not teach which mutation will be indicative of Paget's disease, nor does the specification have any working examples that statistically associate a mutation in any chondroitin sulfate synthase protein with pagets disease of bone.

The specification asserts a method for extracting DNA from blood to analyzed nucleotide sequence of confronting sulfate synthases (pages 38-39). Example 1, demonstrates obtaining blood samples and analyzed the samples for nucleotide sequence. The specification assert that the DNA was obtained and was used as template to amplify exons in the genes of chondroitin sulfate synthase and using these fragments the

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nucleotides sequence were analyzed by conventional technique and compared with those of genes of normal types of the respective chondroitin synthase and one could easily check for mutations or single nucleotide polymorphisms. However, this example demonstrates the routine experimentation to screen for mutations but does not demonstrate associating any mutation with Paget disease of the bone. Example 1 does not demonstrate predictably correlating a mutation with a gene encoding for a chondroitin sulfate synthase protein and its association with Paget's disease of the bone.

The specification does not teach providing a nucleic acid sample from any human or non-human with any Paget disease of bone and then identifying a mutation within chondroitin sulfate synthase protein. The specification does not associate any variant of chondroitin sulfate synthase protein with any disease, much Paget disease of the bone.

The specification does not provide any guidance with the status of the human, non-human and predictably correlating Paget disease of the bone to any polymorphism in chondroitin sulfate synthase protein. The specification does not provide any guidance on determining the status of a human and correlating this status with any polymorphisms. Based on the teaching in the specification it is unclear how the detection of any mutation in a gene of chondroitin sulfate synthase protein would allow for the determination or characterization of Paget disease, much less determine a human's response to any therapeutic compound. For example, if a mutation was found in any gene coding for a chondroitin synthase protein in a human, the skilled artisan would not be able to predictably correlate the presence of any polymorphism with the ability to associated Paget disease of the bone, as the specification does not teach any correlating any

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mutation with a gene coding for chondroitin synthase protein and Paget's disease of the bone.

The specification does not teach a study of humans with any known diseases, much less any Paget disease of the bone, the specification asserts the number of individuals that were assessed for detecting a specific polymorphism but does not teach any disease associated with these individuals. The specification does not provide a control study, a predictive value, or an association with the polymorphism and any disease.

The following is unclear from the teaching in the specification. The specification does not teach an association of a gene coding for chondroitin synthase protein, much less any of its mutations with Paget disease of the bone. The specification provides no teaching of how the identification of any mutation within SEQ ID No. 1 would result in diagnosis or assessment of Paget disease of the bone. For example, if a patient had a mutation in a gene coding for chondroitin synthase gene, the skilled artisan would not be able to predictably correlate the human's associated with Paget's disease of the bone based on the presence of the mutation.

The specification envisions hypothetical situations where correlation of mutation of a gene coding for a chondroitin synthase protein could be used to determine an association with Paget's disease of bone. The specification appears to be conceiving of possible scenarios where any mutation in SEQ ID No. 1 or gene encodes for SEQ ID No. 2 could be correlative to Paget disease of bone. However, based on the teaching in the specification is unclear how one of skill in the art could predictably correlate a mutation

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in “any gene coding for a chondroitin synthase protein”, much less any mutation in SEQ ID no. 1 and its association with Paget’s disease of the bone.

Working Examples

The specification demonstrates working examples of extracting DNA from blood (see example, page 36). The specification demonstrated that the DNA obtained was amplified the exons in the genes of chondroitin sulfate synthase with the aid of primer. The specification demonstrates that the nucleotide sequences of the genes were analyzed by a conventional technique and compared with those of the gene of normal types of respective chondroitin synthase and in this way one could easily check for the presence of mutations and single nucleotide polymorphisms (see page 36). However, the specification does not demonstrate or describe “normal types of respective chondroitin synthase” are these genes of other species, genes from other types of diseases, genes from within the same species but with different alterations in biopathways, disorders, diseases, etc. The specification does not define normal type of the respective chondroitin synthase. Furthermore, the specification does not demonstrate a working example of a mutation and its association with Paget disease in any human or non-human. The specification does not provide any indication of the status of these individuals from which DNA was obtained. The specification does not provide any working examples of obtaining a nucleic acid sample from any human or non human with any paget’s disease of bone and associating a mutation in a gene coding for chondroitin synthases, wherein the chondroitin synthase protein is a glycosyltransferase having activity for transferring a D-glucuronic acid residue or an N-acetyl-D-galactosamine residue to the saccharide residue at the non-reducing terminal of chondroitin or is glycosyltransferase by means of which a

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xylose residue linked to an amino acid residue has D-galactose linked thereto by a β 1,4-glycoside linkage or a mutation in SEQ ID No. 1 or a gene encoded by SEQ ID No.2.

The specification does not provide any working example of correlating the identify of any mutation within SEQ ID No. 1 in a human or non-human and its associated with Paget's disease of the bone.

The unpredictability of the art and the state of the prior art

There is a large body of knowledge in the prior art related to polymorphisms in general, and their association with diseases or disease states, as well as drug or therapeutic response. However, the art is highly unpredictable with regard to the functionality of polymorphic sites in genomic DNA. After a screening assay identifies polymorphisms, it is unpredictable whether any such polymorphisms would be associated with any phenotypic trait, such as a disease state, a physiological state, or drug metabolism or response.

Post filing art, Kroese et al. (Genetics in Medicine, vol 6 (2004), p. 475-480) teach genetic tests are heterogeneous in nature and the exact characteristics of a particular genetic test to be evaluated must be tightly defined. Kroese et al. teach that a particular genetic condition may be caused by more than one gene and these variations may be due to deletions and insertions not detected by routine sequence methods. (see page 476, 2nd column, last paragraph). Kroese et al. teach that genetic test is shorthand to describe a test to detect a particular genetic variant for a particular disease in a particular population and for a particular purpose and that it should not be assumed that once the characteristics of a genetic test are evaluated for one of these reasons that the evaluation will hold or be useful for other purposes and all measures of the test performance should be presented

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with their 95% confidence intervals (see page 477, 1st column, 1st and 2nd full paragraph).

Kroese et al. teach that the limitations of our genetic knowledge and technical abilities means that for the moment there are likely to be gaps in the information needed to complete a thorough evaluation of many genetic tests (see page 479, 2nd column, last paragraph). Additional post filing art reveals that most gene association studies are typically wrong. Lucentini (The Scientist, 2004, Vol 18, page 20) teach that it strikingly common for follow-up studies to find gene-disease associations wrong (see page 2, 1st paragraph). Lucentini teaches that two recent studies found that typically when a finding is first published linking a given gene to a complex disease there is only roughly a one-third chance that the study will reliably confirm the finding (see page 2, 3rd paragraph). Lucentini teaches that bigger sample sizes and more family-based studies, along with revising statistical method, should be included in the gene association studies (see page 3, 2nd paragraph).

In the instant case, the specification only provides information on a sequence of a chondrotin sulfate synthase protein, SEQ ID No1, but provides no guidance that a mutation within a gene coding for a chondrotin sulfate synthase protein has any effect whatsoever on association or diagnostic effect of Paget's disease of bone. Neither the art nor the specification teaches a polymorphism or variant of any chondrotin sulfate synthase proteins are associated with any Paget disease in any individual. The prior art supports the unpredictability of this area of technology.

Level of Skill in the Art

The level of skill in the art is deemed high.

Quantity of Experimentation

Given the lack of guidance in the specification with regard to correlation of any variant of any gene coding for a chondroitin synthase protein with any cardiovascular Paget disease of the bone and lack of association between any variant of SEQ ID No. 1 or a gene the encodes for the amino acid SEQ ID No. 2 to any paget disease of bone and the lack of guidance with regard to which mutations with the large genus of genes would result in any human and non human association with paget disease and would be identified by a variant of any of gene encompassed by broad definition of gene coding for chondroitin synthase protein the quantity of experimentation in this area is extremely large. The skilled artisan would have to determine a predictable correlation between a large genus mutations within the large gene of "gene coding for a chondroitin synthase protein" and any Paget disease of the bone. To practice the invention as broadly as it is claimed, the skilled artisan would have to determine which mutations within the many different genes encompassed by "gene condign for a chondrotoin synthase protein" in many different individuals, human and non human with many different diseases, and then determine if each mutation is associated with paget disease of bone. The skilled artisan would have to perform an extremely large amount of trial and error analysis in a large study to determine if mutations with the large genus of "gene condign for a chondrotoin synthase protein" and the mutations in the specific sequence SEQ ID No 1 of SEQ ID No. 2 is in fact associated with any paget disease of bone. There is still a significant amount of unpredictably in identifying variants within a gene, a skilled artisan would have to detect the sequence of multiple gene coding for a chondroitin synthase protein in

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a large study pool to determine the specific variants that identify only paget disease of bone. This would require a large amount of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps. Thus given the broad claims in an art whose nature is identified as unpredictable, the lack of guidance on how to predictably correlate variants of the large genus of “genes coding for a chondroitin synthase protein” with any Paget disease, the large quantity of research required to define the lack of guidance provided in the specification, the absence of working examples, and the negative teaching in the prior art balanced only against the high level of skill in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to make the claimed invention.

Conclusion

10. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912.

The examiner can normally be reached on M-F 9am-5pm.

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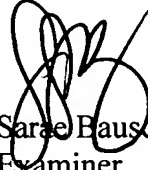
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

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Sarah Bausch, PhD.
Examiner
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